UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2018 P 3103-2
Program	Step Therapy
Medication	Ingrezza® (valbenazine)
P&T Approval Date	11/2017, 11/2018
Effective Date	2/1/2019; Oxford only: N/A

1. Background:

Step therapy programs are utilized to encourage use of lower cost alternatives for certain therapeutic classes. This program requires a member to try Austedo® before providing coverage for Ingrezza for the treatment of tardive dyskinesia.

Ingrezza and Austedo are both a vesicular monoamine transporter 2 (VMAT2) inhibitors indicated for the treatment of adults with tardive dyskinesia.

Members currently on Ingrezza therapy as documented in claims history will be allowed to continue on their current therapy. Members new to therapy will be required to meet the coverage criteria below.

2. Coverage Criteria[a]:

A. Tardive Dyskinesia

1. **Ingrezza** will be approved based on **all** of the following criteria:

   a. Diagnosis of tardive dyskinesia

   -AND-

   b. **One** of the following

      (1) History of failure, contraindication, or intolerance to Austedo (deutetrabenazine)

      -OR-

      (2) **Both** of the following:

         (a) Patient is currently on Ingrezza therapy

         -AND-

         (b) Patient has **not** received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from the Neurocrine Biosciences sponsored Inbrace™ program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Ingrezza*

*****Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from the Neurocrine Biosciences sponsored Inbrace™ program **shall be required** to meet initial authorization criteria as if patient were new to therapy.

Authorization will be issued for 12 months.

B. <u>Other Diagnoses</u>

1. Ingrezza will be approved

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Medical Necessity, Notification, and/or Supply limits may be in place

4. References:

1. Ingrezza Prescribing Information, Neurocrine Biosciences, Inc. August 2018.
2. Austedo Prescribing Information. Teva Pharmaceuticals Inc. August 2017.
3. Waln O, Jankovic J: An update on tardive dyskinesia: from phenomenology treatment. Tremor Other Hyperkinet Mov (N Y) 2013; 3: tre-03-161-4138-1.

Program	Step Therapy - Ingrezza (valbenazine)
Change Control	
11/2017	New program
11/2018	Annual review. No changes to clinical coverage criteria. Updated reference.